

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: May 15, 2008

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number	10/522,664
Filing Date	7/31/2003
First Named Inventor	Heinz-Josef Lenz
Art Unit	1634
Examiner Name	Carla J. Myers
Attorney Docket Number	064189-0604

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
P1	2006-0115827		6/1/2006	Lenz	
P2	2007-0218487		9/20/2007	Lenz	
P3	2007-0244083		10/18/2007	Lenz	
P4	2007-0207486		9/6/2007	Lenz	
P5	2006-0121526		6/8/2006	Danenberg	
P6	6,573,052		6/3/2003	Danenberg	
P7	6,602,670		8/5/2003	Danenberg	
P8	7,049,059		5/23/2006	Danenberg	
P9	7,132,238		11/7/2006	Danenberg	
P10	2004-0265813 A1		12/30/2004	Takechi et al.	

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Application Document Serial Number-Kind Code ² (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
U1	09/715764		11/15/2000	Lenz et al.	
U2	PCT/US2008/000650		1/17/2008	Lenz	
U3	PCT/US2008/000715		1/17/2008	Lenz	
U4	PCT/US2008/051527		1/18/2008	Lenz et al.	
U5	PCT/US2008/000651		1/17/2008	Lenz et al.	
U6	PCT/US2008/000661		1/17/2008	Lenz et al.	
U7	PCT/US2008/000685		1/17/2008	Lenz	
U8	PCT/US2008/000660		1/17/2008	Lenz et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ⁴ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
F1	WO 02/057489		7/25/2002	Response Genetics, Inc.	
F2	WO 02/061128		8/8/2002	Response Genetics, Inc.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov/patent/ptabusin/901.04. 3 Enter Office that issued the document by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of filing of the European application is required. 5 Kind of document by the appropriate symbols as indicated in the document under WIPO Standard ST.16 if possible. 6 Appropriate is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: May 15, 2008

(use as many sheets as necessary)

Sheet 2 of 4

Complete if Known

Application Number	10/522,664
Filing Date	7/31/2003
First Named Inventor	Heinz-Josef Lenz
Art Unit	1634
Examiner Name	Carla J. Myers

Attorney Docket Number 064189-0604

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² Number ³ Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	F3	WO 2007/064957	6/7/2007	University of Southern California		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	D1	IQBAL and LENZ (2001) "Determinants of prognosis and response to therapy in colorectal cancer," <i>Curr. Oncol. Rep.</i> 3(2):102-108	
	D2	IQBAL et al. (2003) "Targeted therapy and pharmacogenomic programs" <i>Cancer</i> 97:2076-2082	
	D3	IQBAL et al. (2003) "Molecular predictors of treatment and outcome in colorectal cancer," <i>Curr Gastroenterol Rep</i> 5(5):399-405	
	D4	IYER and RATAIN (1998) "Pharmacogenetics and cancer chemotherapy" <i>Eur. J. Cancer</i> 34:1493-1499	
	D5	LENZ (2002) "Pharmacogenetic determinants of clinical outcome and toxicity in colon cancer," <i>Eur J Cancer</i> 38(Suppl. 7):S68 #212	
	D6	LENZ (2003) "Pharmacogenomics in colorectal cancer," <i>Semin Oncol.</i> 30(4 Suppl 15):47-53	
	D7	LENZ et al. (1997) "Molecular markers as indicators of response and outcome in primary gastric cancer" <i>Prog Gastric Cancer Res</i> 2:1295-1300	
	D8	LENZ et al. (1998) "Thymidylate synthase (TS) and ERCC1 mRNA expression in patients with inflammatory bowel disease (IBD)," <i>Proc ASCO</i> 17:562a	
	D9	LENZ et al. (2002) "A multivariate analysis of genetic markers for clinical response to 5-FU/oxaliplatin chemotherapy in advanced colorectal cancer. <i>Proc ASCO</i> 21:513	
	D10	LENZ et al. (2003) "Gene expression profile in normal tissue predicts pelvic recurrence in patients with rectal cancer treated with adjuvant chemotherapy," <i>Proc ASCO</i> 22:1185	
	D11	LEONG et al. (2003) "Ribonucleotide reductase M1 and M2 (RR-M1, -M2), cytidine deaminase (CDA), deoxycytidine deaminase (dCDA), deoxycytidine kinase (dCK), and excision repair cross complementation – 1 (ERCC-1) expression in advanced malignancies treated with combined oxaliplatin and gemcitabine," <i>Oncologie</i> 26(3):p46, A3456	

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 609.04, § 3.02. Only one kind code may be issued to the document, by the two-letter code (WIPO Standard ST.1.3). 4 For Japanese patent documents, the indication of the year of the issue of the patent must precede the indication of the publication date. 5 Kind of document by the appropriate symbols as indicated in the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English translation is provided.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: May 15, 2008

(use as many sheets as necessary)

Sheet

3

of

4

Complete if Known

Application Number	10/522,664
Filing Date	7/31/2003
First Named Inventor	Heinz-Josef Lenz
Art Unit	1634
Examiner Name	Carla J. Myers
Attorney Docket Number	064189-0604

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
D12	LEONG et al. (2003) "Ribonucleotide reductase M1 and M2 (RR-M1, -M2), cytidine deaminase (CDA), deoxycytidine deaminase (dCDA), deoxycytidine kinase (dCK), and excision repair cross complementation – 1 (ERCC-1) expression in advanced malignancies treated with combined oxaliplatin and gemcitabine," Proc ASCO 22:3456		
D13	MACHOVER et al. (1996) "Two consecutive phase II studies of oxaliplatin (L-OHP) for treatment of patients with advanced colorectal carcinoma who were resistant to previous treatment with fluoropyrimidines" Ann. Oncol. 7(1):95-98		
D14	METZGER et al. (1996) "ERCC1 expression correlates with response of primary gastric cancer to cisplatin-based chemotherapy," Proc AACR 37:A1350		
D15	METZGER et al. (1996) "Excision repair cross complementing (ERCC)-1 gene in primary gastric cancer: A determinant of response to cisplatin-based chemotherapy," Proc ASCO 15:A505		
D16	METZGER et al. (1998) "ERCC1 mRNA levels complement thymidylate synthase mRNA levels in predicting response and survival for gastric cancer patients receiving combination cisplatin and 5-fluorouracil chemotherapy," J Clin Oncol 16:309–316		
D17	MOERTEL (1994) "Chemotherapy for colorectal cancer" N. Engl. J. Med. 330:1136-1142		
D18	PARK et al. (2002) "ERCC1 polymorphism is associated with differential ERCC1 mRNA levels," Proc AACR 43:1591		
D19	PARK et al. (2003) "ERCC1 gene polymorphism as a predictor for clinical outcome in advanced colorectal cancer patients treated with platinum-based chemotherapy," Clinical Advances in Hematology and Oncology 1(3):162–166		
D20	SHIBATA et al. (1998) "RT-PCR analysis of thymidylate synthetase (TS), ribonucleotide reductase (RR), and ERCC-1 expression in patients (PTS) with locally advanced gastrointestinal (GI) malignancies treated with surgery, intraoperative radiation therapy (IORT) with concurrent 5-FU and external beam radiation (EBRT) with prolonged 5-FU infusion," Proc ASCO 17:562a		
D21	SHIROTA et al. (2001) "ERCC1 and TS expression levels predict survival in patients with advanced colorectal carcinoma under 5-FU/oxaliplatin treatment," Proc ASCO 20:513		
D22	STOEHLMACHER et al. (2002) "The predictive value of thymidylate synthase (TS) and excision repair cross-complementing (ERCC) gene in first- and second-line chemotherapy of patients with colorectal cancer," Amer J Oncol Rev 1:29–32		
D23	STOEHLMACHER et al. (2003) "Pharmacogenetic aspects in treatment of colorectal cancer – an update" Pharmacogenomics 4(6):767-777		
D24	VIGUER et al. (2005) "ERCC1 codon 118 polymorphism is a predictive factor for the tumor response to oxaliplatin/5-fluorouracil combination chemotherapy in patients with advanced colorectal cancer" Clin. Cancer Res. 11:6212-6217		

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 201.04, 3 Enter Office that issued the document. 4 Indicate by a two-letter code (WPO Standard ST.1). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WPO Standard ST.16 if possible. 6 A applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit in the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO																							
INFORMATION DISCLOSURE STATEMENT BY APPLICANT																							
Date Submitted: May 15, 2008 <i>(use as many sheets as necessary)</i>																							
Sheet	4	of 4																					
Complete if Known																							
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33.33%;">Application Number</td> <td style="width: 33.33%; text-align: center;">10/522,664</td> <td style="width: 33.33%;"></td> </tr> <tr> <td>Filing Date</td> <td style="text-align: center;">7/31/2003</td> <td></td> </tr> <tr> <td>First Named Inventor</td> <td colspan="2" style="text-align: center;">Heinz-Josef Lenz</td> </tr> <tr> <td>Art Unit</td> <td colspan="2" style="text-align: center;">1634</td> </tr> <tr> <td>Examiner Name</td> <td colspan="2" style="text-align: center;">Carla J. Myers</td> </tr> <tr> <td colspan="3">Attorney Docket Number</td> </tr> <tr> <td colspan="3" style="text-align: right;">064189-0604</td> </tr> </table>			Application Number	10/522,664		Filing Date	7/31/2003		First Named Inventor	Heinz-Josef Lenz		Art Unit	1634		Examiner Name	Carla J. Myers		Attorney Docket Number			064189-0604		
Application Number	10/522,664																						
Filing Date	7/31/2003																						
First Named Inventor	Heinz-Josef Lenz																						
Art Unit	1634																						
Examiner Name	Carla J. Myers																						
Attorney Docket Number																							
064189-0604																							

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	D25	WATERS and CUNNINGHAM (2001) "The changing face of chemotherapy in colorectal cancer" Br. J. Cancer 84(1):1-7	T ⁶
	D26	YACOUB et al. (2003) "Epidermal Growth Factor and Ionizing Radiation Up-regulate the DNA Repair Genes XRCC1 and ERCC1 in DU145 and LNCaP Prostate Carcinoma through MAPK Signaling" Radiation Res. 159:439-452	
	D27	YUN et al. (2003) "Association of genetic polymorphisms of IL-8 and its receptor CXCR1 and survival of patients with metastatic colorectal cancer treated with 5FU/oxaliplatin" Proc ASCO 22:847	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 001.04, 3 Enter Office that issued the patent or the Office by the word "Foreign". 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 If no code is present by the appropriate symbol as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.